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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,560	04/02/2004	Stephen J. Benkovic	7418/91839	3809

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WELSH & KATZ, LTD
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER	
STAPLES, MARK	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,560	BENKOVIC ET AL.	
	Examiner	Art Unit	
	Mark Staples	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 33-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 33-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 04/02/2006 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/03/04 & 9/28/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect that libraries of nucleic acid sequences are created. The following or similar is suggested: "Methods for creating libraries of nucleic acids using Holliday junctions".

3. The abstract of the disclosure is objected to because it does not accurately describe the claimed invention. The abstract describes a method for amplifying a target nucleic acid sequence, but there is no amplifying step in the claimed invention. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 and hence subsequent dependent claims 34-37 are confusing because there is no direct correspondence for creating a library in the preamble of claim 33 to the subsequent method steps. It is unclear how the library is formed. It is further unclear as to how a plurality of three stranded crossover junctions are formed on the second double-stranded nucleic acid, and whether these crossover junctions are homologous or non-homologous to the second double-stranded nucleic acid. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 33–37 are rejected under 35 U.S.C. 102(b) as being anticipated by Mosig (1998).

Mosig teaches a method (entire reference) comprising:

[a] incubating a first double-stranded nucleic acid with an enzyme with exonuclease activity to form single stranded DNA (see especially Figure 2 and Figure 5e);

[b] treating single stranded DNA regions with a recombination factor to form pretreated single stranded DNA regions (see especially Figure 2 for DNA segments and Figure 5e);

[c] adding a second double-stranded nucleic acid to the single stranded DNA regions to form three stranded crossover junctions (see Figure 2 and Figure 5e);

[d] incubating three stranded crossover junctions with a helicase to form Holliday junctions (see especially Figure 2, Figure 5e, and p. 392, 3rd paragraph); and

[e] resolving Holliday junctions by incubation with an endonuclease (see especially p. 392, 3rd paragraph and Table 1).

Regarding claim 34, Mosig teaches a method wherein the recombination factor is bacteriophage T4 UvsX (see Table 1 on page 384).

Regarding claim 35, Mosig teaches a method wherein the helicase is bacteriophage T4 gene products 41 and 59 (see Table 1 on page 384).

Regarding claim 36, Mosig teaches a method wherein the helicase is bacteriophage T4 UvsW (see Table 1 on page 384).

Regarding claim 37, Mosig teaches a method wherein the endonuclease is bacteriophage T4 gene product 49 (see Table 1 on page 385).

6. Claims 33–34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by West (1992).

West teaches a method (entire reference) comprising:

[a] incubating a first double-stranded nucleic acid with an enzyme with exonuclease activity to form single stranded DNA (see p 622, 1st sentence of 2nd paragraph for "exonuclease activity");

[b] treating single stranded DNA regions with a recombination factor to form pretreated single stranded DNA regions (see especially especially Figure 1 A, Figure 3, Figure 4 *top*, and Figure 5A);

[c] adding a second double-stranded nucleic acid to the single stranded DNA regions to form three stranded crossover junctions (see especially p. 614 section *Three-Stranded DNA Helices as Recombination Intermediates*, Figure 1 A, Figure 3, Figure 4 *top*, and Figure 5A);

[d] incubating three stranded crossover junctions with a helicase to form Holliday junctions (see especially p. 620. 2nd sentence "The . . . gene products form an enzyme . . . that show multiple activities including, . . . [c] a unidirectional DNA helicase"); and

[e] resolving Holliday junctions by incubation with an endonuclease (see especially p 627, section *Enzymes that Cleave Branched DNA structures*).

Regarding claim 34, West teaches a method wherein the recombination factor is bacteriophage T4 UvsX (see p 628, last sentence of 1st paragraph).

Regarding claim 37, West teaches a method wherein the endonuclease is bacteriophage T4 gene product 49 (see especially p 627, section *Enzymes that Cleave Branched DNA structures*).

7. Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Kowalczykowski (1994).

Kowalczykowski teaches a method (entire reference) comprising:

[a] incubating a first double-stranded nucleic acid with an enzyme with exonuclease activity to form single stranded DNA (see especially p. 204 section Biochemical pathway . . ., 3rd sentence: "The exchange of DNA strands" and exonucleases in table on p. 206);

[b] treating single stranded DNA regions with a recombination factor to form pretreated single stranded DNA regions (entire reference, especially abstract);

[c] adding a second double-stranded nucleic acid to the single stranded DNA regions to form three stranded crossover junctions (see especially Figure 1);

[d] incubating three stranded crossover junctions with a helicase to form Holliday junctions (see especially Figure 1); and

[e] resolving Holliday junctions by incubation with an endonuclease (see p. 206, section *RecBCD enzyme, a DNA helicase with nuclease activity*, 3rd & 4th sentences: "The DNA helicase activity can unwind dsDNA with flush or nearly flush . . . dsDNA . . . . The nuclease activities are quite diverse, and include ATP-dependent dsDNA exonuclease, ATP-dependent ssDNA endonuclease, and ATP-stimulated ssDNA exonuclease activities").

Conclusion

8. Claims 33-37 are not free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
September 12, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
9/14/06